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| 10/812,884 | 03/31/2004 | Shoichi Kanayama | 251157US2SX | 4570 |
| 22850 | 7590 | 06/01/2007 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. | | | TALMAN, JAMES R | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 10/812,884 | KANAYAMA ET AL. | |
| Examiner | Art Unit | | |
| James R. Talman | 3709 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 31 March 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 3/31/04 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/23/2004;9/15/2005;3/14/2006.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .
5) Notice of Informal Patent Application
6) Other: ____ .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On page 1, line 18, "acquire" should be changed to --acquires--.

On page 1, line 19, "superimpose" should be changed to --superimposes--.

On page 3, line 18, "substance" should be changed to --substances--.

On page 5, line 10, "These" should be changed to --This--.

On page 5, line 10, "take" should be changed to --takes--.

On page 5, line 20, "as photon density wave propagate" should be changed to -- as a photon-density wave propagates--.

On page 5, line 21, "is" should be changed to --in--.

On page 35, line 10, "subjected" should be changed to --subject--.

On page 42, line 10, "the amount of light absorbed by" should be removed.

On page 51, lines 19 and 20, "79" should be changed to --179--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 21, on page 61, line 1, the word "acoustic" in the second image data generating means is confusing because the second image data generating means uses an ultrasound wave. Examiner suggests changing "acoustic" to --ultrasonic-- to clarify the claim.

As per claim 26, in part (d) of the claim, "detecting an ultrasound image" is confusing. Examiner suggests changing "detecting" to --displaying--.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 5, 6, 12-17, 20-24, and 26-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9, 10, 12, 16, 19, 27, 31, 32, and 38-40 of U.S. Patent No. 6979292. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the patent claims cover common subject matter and achieve the same end result of imaging a subject using a combination of electroacoustic and ultrasonic modalities and because the claims of the instant application are obvious variants of the '292 patent.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 16, and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kruger (US Patent Application Publication 2003/0069491).

As per claim 1, Kruger discloses a non-invasive imaging apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) with a specific wavelength component (paragraph 4), a plurality of two-dimensionally arrayed electroacoustic transducer elements (24, 32), transmission means for

transmitting ultrasonic waves (52, 54), reception means for generating a reception signal from the ultrasonic waves (52, 56), signal processing means for generating volume data by processing a reception signal corresponding to acoustic waves generated in the subject by light radiated from the irradiation unit (46, 48), and signal processing means for generating volume data about a subject morphology by processing a reception signal corresponding to echoes generated in the subject upon transmission of the ultrasonic waves (US imaging system, 52).

As per claim 16, Kruger discloses an imaging method comprising: irradiating a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) containing a specific wavelength component (2-12 cm, paragraph 4), causing a plurality of two-dimensionally arranged electroacoustic transducer elements (24, 32), to receive acoustic waves generated in the subject upon the irradiation of light, transmitting ultrasonic waves in a plurality of directions (54), receiving echoes from the ultrasonic waves (56), generating volume data about a tissue morphology (US imaging system, 52), and generating volume data about a living body function on the basis of the acoustic waves (TACT system and receiver, 46 and 48).

As per claims 21-23, Kruger discloses a subject-information imaging apparatus comprising: irradiation means for irradiation a subject to be examined with light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides), ultrasonic transmission means for transmitting ultrasonic waves (54), electroacoustic conversion means (transducer elements 24, 32), first image data generating means on the basis of the acoustic wave (TACT system and receiver, 48,

and 46) generated in the subject upon the irradiation of light, second image data generating means based on the ultrasonic waves (56), display means (display, 50) for displaying the first image data and the second image data, wherein the ultrasonic wave transmission means is partly commonly used as the electroacoustic conversion means (the sensors on array 24 may be used for conventional ultrasound imaging of the subject tissue, paragraph 37), and wherein the display means displays the first image data and the second image data on the same monitor (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37).

As per claim 24, Kruger discloses a subject-information imaging apparatus which irradiates a subject to be examined with light (irradiating said tissue with Electromagnetic radiation, see abstract), and an ultrasonic wave (produce a narrow sweeping beam of ultrasound, paragraph 37), receives acoustic waves generated in the subject by the light (TACT receiver 46) and the ultrasonic wave (US receiver, 56), converts the waves into electrical signals (US imaging system, 52), and generates and displays the image data (Display, 50).

8. Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Kruger (US Patent No. 5713356).

Kruger discloses a subject-information imaging apparatus (facilitate imaging, see abstract), which irradiates a subject to be examined with light (The electromagnetic radiation may be ... light generated by a Xenon flash tube...., column 4, lines 36-40), receives an acoustic wave generated in the subject by the light (incident electromagnetic waves to produce resultant acoustic waves, see abstract), generates

image data about a volume (..volume to be imaged, column 6, line 12; see also abstract, ... producing images from the transducer signals), and displays the image data (Figure 17).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2-15, 17-20, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491).

As per claim 2, Kruger, as applied to claim 1 above, discloses all the elements of the claimed invention except for the use of optical fibers for the waveguide means. Examiner takes Official Notice that optical fibers are a well-known waveguide means for infrared and visible light. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger to use optical fiber as the waveguide means in order to investigate the subject properties at infrared and visible wavelengths.

As per claims 3 and 4, Kruger further discloses electroacoustic transducer elements that are vertically and horizontally arrayed (Figure 3) with predetermined gaps between elements. Kruger does not explicitly disclose placing waveguides in the gaps between the electroacoustic transducer elements. In any event, the waveguides and

the electroacoustic elements must be in close proximity to one another in order for the ultrasonic and photoacoustic sources to be imaging approximately the same field of view. It would have been obvious to a person having ordinary skill in the art at the time of the invention to place the waveguides in the gaps between elements because it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Furthermore, this arrangement of waveguides and elements would result in each waveguide being surrounded by four elements.

As per claims 5 and 6, Kruger further discloses scanning means (scanning system, paragraph 37), accomplished by rotating the waveguides (18) and detector array (24) to multiple angular positions (paragraph 31) and further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of a waveguide (Figure 1).

As per claims 7, and as applied to claim 2 above, Kruger further discloses radiating light beams (electromagnetic radiation, see abstract) from not less than two optical fibers (at least eight waveguides, Figure 6A) whose end portions are spaced apart by not less than a predetermined distance.

As per claim 8, and as applied to claim 7 above, Kruger further discloses generating a reception signal corresponding to acoustic waves generated by irradiation of the light (TACT system and receiver, 46 and 48), from electrical signals from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claim 9, and as applied to claim 2 above, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a plurality of end portions of optical fibers (waveguides, Figure 1; eight positions, Figure 6).

As per claim 10, and as applied to claim 9 above, Kruger further discloses generating a reception signal from electrical signals (TACT system and receiver, 46 and 48), from a predetermined number of transducer elements (24, 32) near an end portion of an optical fiber (waveguide, Figure 1).

As per claims 11 and 12, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claim 13, Kruger further discloses forming a 2-dimensional image (paragraph 10). Furthermore, forming a 2-dimensional image from a 3-dimensional volume of data inherently requires selecting a single slice from the 3-dimensional volume.

As per claims 14 and 15, Kruger further discloses displaying (display, 50) living body function image data (TACT data, paragraph 37) and morphology image data (ultrasound image, paragraph 37), with said morphology image data superimposed on (overlaid, paragraph 37) said living body function image data on the display. Kruger does not explicitly disclose displaying the images side by side. It would have been obvious to a person having ordinary skill in the art at the time of the invention to display

the images side by side, as it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

As per claim 17, Kruger further discloses sequentially radiating light (electromagnetic radiation) from said plurality of radiators by rotating the apparatus in order to collect signals from a sequence of multiple angular positions (paragraph 31).

As per claims 18, and 19, Kruger further discloses simultaneously radiating light (synchronized electromagnetic radiation, paragraph 16) from a predetermined number of discrete positions (eight positions, Figure 6).

As per claim 20, Kruger further discloses alternately (separately) performing (Simultaneously, or as a separate imaging modality, paragraph 37) the irradiation of light and the transmission of ultrasonic waves.

As per claim 29, the phrase "for diagnosing disease such as breast cancer" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) with a specific wavelength component (paragraph 4), first electroacoustic conversion means (two-dimensional array of transducer elements 24, 32), first image data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for displaying the first

image data and the second image data (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37).

Kruger does not explicitly disclose a second electroacoustic conversion means for converting components of the ultrasonic waves transmitted by the ultrasonic wave transmission means but, rather, uses the first electroacoustic conversion means for converting both the acoustic waves and the ultrasonic waves. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art, *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

As per claim 30, the phrase "for determining a distribution of the concentration of an analyte" is intended use language and is not given patentable weight because it is not further reflected in the body of the claim. Kruger discloses an apparatus comprising: a light-generating unit (electromagnetic energy from an external source, paragraph 30), light irradiation and waveguide means (18, 84) for guiding and radiating light (electromagnetic radiation, see abstract; radiation occurs from open end of waveguides) with a specific wavelength component (paragraph 4), first electroacoustic conversion means (two-dimensional array of transducer elements 24, 32), first image data generating means (46, 48), transmission means for transmitting ultrasonic waves (52, 54), on means (86), second image data generating means on the basis of the second electroacoustic conversion means (US imaging system, 52), and a display means for

displaying the first image data and the second image data (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37).

Kruger does not explicitly disclose a second electroacoustic conversion means for converting components of the ultrasonic waves transmitted by the ultrasonic wave transmission means but, rather, uses the first electroacoustic conversion means for converting both the acoustic waves and the ultrasonic waves. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Ertlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

11. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491) in view of Chou (US Patent No. 6049728).

Kruger discloses a method of imaging the human breast (radiation in a breast, paragraph 27) comprising: a probe having two-dimensionally arrayed ultrasound imaging elements (Figure 7), irradiating the tissue with light pulses (pulsed radiation, paragraph 9) to generate a photoacoustic signal, detecting the photoacoustic signal using ultrasound transducers (24, 32), and generating and displaying an ultrasound image and a photoacoustic image (an ultrasound image of the tissue may be .. overlaid with ...the TACT-generated image, paragraph 37), using common acoustic and ultrasound detection elements (86).

Kruger does not explicitly disclose separate acoustic and ultrasonic detection elements but, rather, uses same set of detection elements to detect both signals and does not explicitly disclose irradiating the tissue with light having wavelengths within an absorption spectral band of hemoglobin. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Kruger to use separate electroacoustic conversion means as it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, separate arrays of transducer elements would avoid the need for filtering of the two signals.

Chou discloses using a wavelength corresponding to an absorption spectral band of hemoglobin (electromagnetic energy at wavelengths corresponding to the absorption characteristics of the analyte, column 3, lines 13-15; monitor.... Hemoglobin, column 4, line 37). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the invention of Kruger by using a wavelength corresponding to an absorption spectral peak of hemoglobin in order to generate images with high specificity to the presence of blood within the breast.

12. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kruger (US Patent Application Publication 2003/0069491) in view of Chou (US Patent No. 6049728), and further in view of Diab et al (US Patent Application Publication 2003/0097049).

The Kruger/Chou combination, as applied to claims 26 above, discloses all the elements of the claimed invention except that it does not explicitly disclose using a

wavelength of light in the spectral range between 530 nm and 1300 nm. Diab et al discloses a relative absorption spectrum of oxygenated and de-oxygenated hemoglobin from 300 nm to 1000 nm showing various absorption peaks and valleys, etc. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the combination of Kruger/Chou to use wavelengths in the range from 530 nm to 1300 nm, as this range is very close to the spectral absorption range for hemoglobin disclosed in Diab et al and therefore wavelengths in this range could be chosen to maximize the signal from the hemoglobin or to provide best contrast between oxygenated and de-oxygenated hemoglobin.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US5713356, Kruger. Breast imaging, microwaves.

US6102857, Kruger. Breast scanner using photoacoustic effect.

US6979292, Kanayama et al. Double patenting with instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Talman whose telephone number is 571-270-3029. The examiner can normally be reached on 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynda Jasmin can be reached on 571-270-3033. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James R Talman
Examiner
Art Unit 3709

Jrt

Lynda Jasmin 5/25/01
LYNDA JASMIN
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